

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. 09/966,441 09/28/2001 Christopher E. Szymczak MCP-284 5360 01/25/2006 EXAMINER 27777 7590 PHILIP S. JOHNSON KWON, BRIAN YONG S JOHNSON & JOHNSON ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 1614

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/966,441	SZYMCZAK ET AL.
Office Action Summary	Examiner	Art Unit
	Brian S. Kwon	1614
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on <u>09 November 2005</u> .		
2a) This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
<ul> <li>4) ☐ Claim(s) 29-38 is/are pending in the application.</li> <li>4a) Of the above claim(s) _ is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 29-38 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)	_	
1) Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail Da	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		atent Application (PTO-152)

Application/Control Number: 09/966,441

Art Unit: 1614

#### **DETAILED ACTION**

## **Status of Application**

- 1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114.
- 2. By Amendment filed November 09, 2005, claims 1-28 have been cancelled; claim 29 has been amended; and claims 30-38 have been newly added. Claims 29-38 are currently pending for prosecution on the merits.
- 3. With respect to the instant claim 29, it appears that the Applicant amended the claim 29 in view of the Examiner's indication of Allowable Subject Matter (pages 7-9 of O.A. mailed May 5, 2005) and the Advisory Action mailed September 09, 2005. Although the Applicant's cooperation to place the claimed invention in better form for the allowance is appreciated, the Examiner, in reconsideration, determines that the application is not ready for the allowance yet for the following reasons. Accordingly, the Examiner withdraws the indicated allowability of the claim 29 (page 9 of O.A. mailed May 5, 2005).

#### Allowable Subject Matter

4. The following claim 29 drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration: "A solid oral dosage unit comprising a compressed admixture of a proportionate amount of simethicone, silicified microcrystalline cellulose, and magnesium aluminometasilicate, wherein the proportionate amounts, by weight, of the admixtures of simethicone, silicified microcrystalline

Application/Control Number: 09/966,441

Art Unit: 1614

cellulose and magnesium aluminometasilicate is about 1: about 0.5 to about 0.85: about 0.9 to about 1.30 per solid oral dosage unit".

### Claim Objections

5. Claim 31 is objected to because of the following informalities: "wher in" in line 1 should be corrected as "wherein".

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 29 recites that an adsorbent is selected from the group consisting of magnesium aluminometasilicate and silicified microcrystalline cellulose. According to the claimed language, the final composition of the claimed invention could only contain single adsorbent selected from magnesium aluminometasilicate or silicified microcrystalline cellulose, not both.

Since the criticality of the instant application lies in the specific proportionate amounts of simethicone:magenisum aluminometasilicate:silicified microcrystalline cellulose, about 1: about 0.5 to about 0.85:about 09 to about 1.30 per solid dosage unit, in said composition, the final composition resulted from the selection of single adsorbent, not mixture of aluminometasilicate and silicified microcrystalline cellulose, leaves the reader in doubt as to the meaning of the

Application/Control Number: 09/966,441

Art Unit: 1614

invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

With respect to claims 37 and 38 (which is dependent claim of claim 37), there is insufficient antecedent basis for "the compressed admixture" in the independent claim 29.

#### **Conclusion**

- 7. No claim is allowed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon Patent Examiner AU 1614